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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,393	04/14/2005	Gerard Coudert	SERVIER 454 PCT	9112

25666 7590 06/21/2006

THE FIRM OF HUESCHEN AND SAGE
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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/531,393

Applicant(s)

COUDERT ET AL.

Examiner

Charanjit S. Aulakh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 19-22 and 29-34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/16/06
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 6/16/06
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

1. According to a preliminary amendment, the applicants have canceled claims 1-18 and furthermore, have added new claims 19-36.
2. Claims 19-36 are now pending in the application.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 19, 23-25 and 29-36, drawn to compounds of formula (I) where A represents formula (a), R2 and R3 do not form a bond, pharmaceutical compositions containing these compounds and a method of using these compounds.

Group II, claim(s) 19-22 and 29-36, drawn to compounds of formula (I) where A represents formula (a), R2 and R3 do form a bond, pharmaceutical compositions containing these compounds and a method of using these compounds.

Group III, claim(s) 19 and 26-36, drawn to compounds of formula (I) where A represents formula (b), R2 and R3 do form a bond, pharmaceutical compositions containing these compounds and a method of using these compounds.

Group IV, claim(s) 19 and 29-36, drawn to compounds of formula (I) where A represents formula (b), R2 and R3 do not form a bond, pharmaceutical compositions containing these compounds and a method of using these compounds.

4. The inventions listed as Groups I, II, III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Art Unit: 1625

There is no common core which in the Markush Practice, is a significant structural element shared by all of the alternatives; see PCT Administrative Instructions Annex B Part I (f) (i) (B) (1). In the instant case, variables A, R2 and R3 are critical for the common core of the instant compounds.

5. During a telephone conversation with the applicant's attorney, Ms. Michele Cudahy on June 16, 2006, a provisional election was made with traverse to prosecute the invention of group II, claims 19-22 and 29-36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the filing date of the foreign priority document FR 02. 12965 is listed as 10/18/2001. However, according to this document, the filing date is 10/18/2002. An appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1625

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating leukaemia, prostate carcinoma, non-small-cell lung carcinoma, colon carcinoma and epidermoid carcinoma, does not reasonably provide enablement for treating every known cancer in the art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, unpredictability, the state of the prior art and the breadth of claims.

The specification demonstrates inhibitory effect of a single compound (example 20) in few cell lines (murine leukaemia, prostate, non-small-cell lung, colon and epidermoid carcinoma) in vitro (see examples 43 and 44 on pages 60-61). Based on these data, the instant compounds will have utility in treating leukaemia, prostate carcinoma, non-

Art Unit: 1625

small-cell lung carcinoma, colon carcinoma and epidermoid carcinoma. There is no teaching in the specification regarding any mechanism of action (such as inhibition of specific enzymes etc.) of instant compounds as well as no guidance or direction to show how the instant compounds will have utility in treating every known cancer in the art. There is no teaching in the instant specification or prior art regarding well established utility for treating every known cancer with structurally closely related compounds. In the prior art, structurally closely related compounds (see U.S. Patent 5,705,511, cited on applicants form 1449) are shown to have inhibitory effect in prostate cell line (see table IX in column 26) with huge variations (IC50 values ranging from 380 nM to more than 10, 000 nM). Based on this prior art reference, there appears to be lot of unpredictability regarding inhibitory effect of these compounds on cancer cell lines. The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of variables R1, R4, W1, Z, Z1, Y and Z2 and therefore, in absence of such teachings, guidance, presence of working examples and unpredictability, it would require undue experimentation to demonstrate the inhibitory effect of instant compounds in every known cancer cell line in vitro and hence their utility for treating every known cancer.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection

desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 35 recites the broad recitation living animal, and the claim also recites human which is the narrower statement of the range/limitation.

12. Claims 19 and 29-36 are objected for containing non-elected subject matter.

Allowable Subject Matter

13. Claims 20-22 are objected to as being dependent upon an objected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

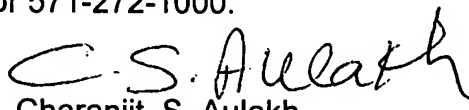
The instant compounds directed to the elected group are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Hudkins (U.S. Patent 5,705,511, cited on applicants form 1449) discloses fused pyrrolocarbazoles of formulae Ia and Ib (see col. 8 and table 1 in col. 10) which are closely related to instant compounds. However, the compounds of Hudkins differ from the instant compounds in lacking instant variable Y and furthermore, there is no

teaching or motivation in the prior art to modify the compounds of Hudkins to prepare the instant compounds.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Charanjit S. Aulakh
Primary Examiner
Art Unit 1625